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5 APPLICATION

6 for

7 UNITED STATES PATENT

8 on

9 METHOD AND COUPLING APPARATUS FOR FACILITATING
10 AN VASCULAR ANASTOMOSES

11 by

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This invention was disclosed in a Disclosure Document numbered 448542 entitled "Anastomosis Coupling Apparatus" and submitted to the Patent and Trademark Office on December 8, 1998.

FIELD OF THE INVENTION

This invention relates generally to the field of surgery and, more particularly, to a method and device for performing conventional or minimally invasive bypass surgery. More specifically, the present invention relates to a method and a device to perform end-to-side vasculature anastomoses with either conventional or minimally invasive methods coupling a conduit vein or artery with a normal segment of a coronary or other vessel distal to the diseased, narrowed segment.

BACKGROUND OF THE INVENTION

In the context of coronary vessel disease, the flow of oxygenated blood to the myocardium of the heart is inhibited by a stenosis or obstruction on one or more of the coronary arteries. Flow can be restored by providing a coronary artery bypass graft (CABG). In this procedure, connection is established between the aorta and a normal segment of the diseased coronary vessel using

1 a free vein (e.g. saphenous vein) or arterial (e.g. radial)
2 segment. Alternatively, a distal segment of an vessel (e.g.
3 internal mammary, gastroepiploic etc) is mobilized, severed and
4 attached to the coronary vessel. Both the free grafting and the
5 mammary artery, gastroepiploic artery grafting can be performed
6 during open chest surgery with or without cardiopulmonary bypass
7 ("on/off pump") or using less invasive ("minimally invasive")
8 techniques, ultimately, thoracoscopy without opening the chest.
9 One problem the surgeon faces during any of these above
10 procedures is how to grab the bypassing vessel since the vessel
11 with the interrupted blood flow becomes flabby and hard to
12 handle, does not keep the preferred (i.e. a elongated) shape to
13 fit exactly the aperture on the target vessel. Also, the
14 bypassing vessel needs extremely gentle handling to prevent even
15 minimal damage that can lead to future proliferation and
16 eventually, narrowing of either the vessel and/or that of the
17 anastomosis. Acutely, rough handling of the live conduit artery
18 (i.e. internal mammary artery) might lead irreversible spasm.
19 Therefore, it is imperative to have an apparatus, which makes:

- 20 1) grabbing of the conduit vessel easy and less traumatic,
- 21 2) the anastomosis site of the bypassing or blood supplying
22 vessel follows the desired shape, and
- 23 3) the proper sizing of the target aperture to mimic the
24 size and configuration of the bypassing or blood supplying distal
anastomosis aperture.

[illegible]

In the preferred embodiment, the present invention relates to an apparatus and method for facilitating end-to-side vascular anastomoses procedure, whereby the present invention acts as a coupling apparatus between a first, blood supplying hollow organ, e.g. the LIMA, radial artery, or a saphenous vein and the side wall of second hollow organ, typically one of the major coronary arteries, such as the left coronary artery (LCA), right coronary artery (RCA) or the circumflex (CX).

1 staples. The anastomosis coupling apparatus can be fitted with a
2 means for controlling its location and configuration within a body
3 cavity using standard incision technologies presently known by
4 those skilled in the art.

5
6 The output end of the coupling apparatus is appropriately
7 prepared for securement means by attachment with staples or sutures
8 and in some cases, by means of additional adhesive or glue
9 application to increase the security of the attachment. Then, the
10 prepared coupling apparatus is positioned in close proximity to the
11 desired anastomosis site on a coronary vessel and finally engaged
12 to the coronary vessel site.

13
14 Now blood flow is established from the blood supplying vessel
15 to the coronary distal to the obstruction, supplying the myocardial
16 tissues once nourished by the native unoccluded vessel. All
17 relatively trivial vascular, abdominal, or thoracotoic incisions
18 made during the course of the procedure are treated according to
19 standard practices. The patient is monitored for period of time to
20 verify that the anastomosis has been successful and that no leakage
21 is occurring from the joint.

22
23 The method and devices of the present invention find
24 particular application for performing vascular anastomoses,
including, in particular, coronary bypass between an arterial
source and an obstructed coronary vessel. In particular, the

1 method and devices of the present invention find particular
2 application in establishing an anastomoses between the severed end
3 of a supplying vessel e.g. the left internal mammary artery
4 ("LIMA") and the side wall of a coronary artery e.g. the left
5 anterior descending coronary artery ("LAD"), circumflex ("CX") or
6 right coronary artery ("RCA").

7 BRIEF DESCRIPTION OF THE DRAWINGS

8
9 FIG. 1 is a schematic perspective view of a patient in
10 undergoing a coronary bypass procedure, showing the placement
11 and anastomosis coupling apparatus in accordance with the present
12 invention.

13
14 FIG. 2 is a lateral view of the first embodiment of the
15 anastomosis coupling apparatus adapted for use in the coronary
16 bypass procedure shown in FIG. 1.

17 FIG. 3 is a posterior view of the anastomosis coupling
18 apparatus showing a hinge mechanism.

19
20 FIG. 4 is an angled superior view of the anastomosis coupling
21 apparatus.

22 FIG. 5 is an anterior view of the anastomosis coupling
23 apparatus showing a anterior opening or slot.
24

1 FIG. 6 is a perspective view showing a coronary vessel
2 prepared for engagement with the anastomosis coupling apparatus.

3
4 FIG. 7 is a perspective view of the coupling apparatus in an
5 opened position and showing a representation of using an adhesive
6 or gluing means applied between the outside surface of the severed
7 end of the arterial source and inner surface of the anastomosis
8 coupling apparatus thereby securing the two surfaces together.

9 FIG. 8 is a perspective view showing the outside surface of
10 the severed end of the supply arterial source and anastomosis
11 coupling apparatus secured together. The engaged blood supplying
12 source and anastomosis coupling apparatus are also shown being
13 advanced toward the prepared coronary vessel for securement.

14 FIG. 9 is a perspective view of the blood supplying vessel
15 and the anastomosis coupling in final position for securement to
16 the coronary vessel with stitches or staples.

17
18 FIG 10. is a schematic perspective view showing the
19 anastomosis coupling apparatus securing the junction between the
20 severed end of the arterial source and the side-wall of the
21 coronary vessel.
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1 FIG. 11 is a lateral view of second embodiment of an
2 anastomosis coupling apparatus adapted for use in the coronary
3 bypass procedure shown in FIG. 1.

4 FIG. 12 is a posterior view of the second anastomosis coupling
5 apparatus showing its back hinge mechanism.
6

7 FIG. 13 is an angled superior view of the second anastomosis
8 coupling apparatus.
9

10 FIG. 14 is an anterior view of the second anastomosis coupling
11 apparatus showing an anterior slot.
12

13 DESCRIPTION OF THE PREFERRED EMBODIMENT 14

15 The present invention can be used as a means to facilitate the
16 anastomosis procedure and decrease the likelihood of leakage in
17 conventional open-chest, small incision bypass surgeries on and off
18 cardiopulmonary bypass. These procedures are well known by those
19 skilled in the art and recitation of these procedures is not
20 reproduced here.

21 Alternately, in closed chest thoroscopic methods, the
22 present invention can employed as describe herein. In preparation
23 for the surgical procedure of the present invention, the patient is
24

1 placed on the operating table in a supine position, and general
2 anaesthesia administered. The patient is selectively intubated
3 using conventional methods with a double-lumen endotracheal tube,
4 thereby permitting the left lung to be deflated. The patient is
5 then placed in a lateral decubitus position on his right side.
6 Next, based upon the pathology and anatomy of the patient, the
7 surgeon identifies a suitable position for insertion of a Beress
8 insufflation needle or other suitable needle. Typically, this
9 needle will be inserted between the fifth or sixth intercostal
10 space along the anterior axillary line and into the region between
11 the parietal pleura and the pericardium. The parietal pleura and
12 pericardium are then separated by conventional gas dissection, and
13 the Beress needle is removed.

14 In order to perform the anastomosis procedure, it is first
15 desirable to visualize the coronary vessel using conventional
16 angiographic techniques. Typically, the surgeon will already have
17 an angiogram of the affected coronary vessel available as a result
18 of the earlier diagnosis of the necessity for the coronary bypass.
19 Similarly, it is desirable to use conventional angiographic
20 techniques to visualize the arterial source. The location of the
21 stenosis will dictate the proper placement of the secured
22 anastomosis coupling apparatus.

23 For the purpose of an example, the following will define an
24 embodiment that couples the LIMA to the LAD coronary artery. It is

1 contemplated by the Applicant that supplying arteries other than
2 the LIMA, freed segments of veins, radial and other vessels can be
3 used with this apparatus invention and method. Furthermore, other
4 coronary arteries, e.g. the RCA, Circumflex, can be used with this
5 apparatus invention and method.

6 Under the guidance of the endoscopic telescope or conventional
7 endoscopic instruments are used to isolate the a supply vessel from
8 surrounding tissue and the chest wall. A number of considerations
9 are taken into account in determining the site for severing the
10 LIMA 10. Using the angiographic and direct visualization, the
11 surgeon can determine a desirable proposed site for severing which
12 will provide a suitable length of vessel with a diameter that
13 closely matches that of the coronary vessel. A maximum length of
14 the LIMA, 10 can be obtained by severing the LIMA 10 at its distal.
15 end near the diaphragm. In preparation for severing, blood flow to
16 the side branches of the LIMA 10 is interrupted by clipping or
17 cauterizing the branches of the LIMA proximally of the proposed
18 site for severing. Blood flow through the LIMA 10 is interrupted
19 by applying an appropriate located clips. The LIMA 10 is then
20 severed using conventional endoscopic techniques, thereby creating
21 a proximal severed end and a distal severed end.

22 Using conventional endoscopic techniques, the parietal pleura
23 is dissected and the pericardial sac is opened. The endoscopic
24 telescope can be used to visualize the LAD 12 while the LAD 12 is

1 then isolated endoscopically from the surrounding tissue proximally
2 and distally of the proposed site for anastomosis.

3
4 With reference now to the exemplary drawings, and particularly
5 to FIG. 1, there is shown a schematic perspective view of a patient
6 who had undergone an artery-to-artery coronary bypass procedure in
7 accordance with the present invention in which an end-to-side
8 vascular anastomosis is established between the severed end of the
9 a supply vessel, e.g. a by-pass graft or left internal mammary
10 artery ("LIMA") 10 and the side-wall of a coronary artery e.g. left
11 anterior descending coronary artery ("LAD") 12, distally to the
12 site of an stenosis. In this figure, the input end of the
13 anastomosis coupling apparatus is secured to a by-pass graft 10 and
14 the output end of the coupling to the LAD 12 of the heart 14.

15 As shown in FIG. 2, the first embodiment of the anastomosis
16 coupling apparatus 30 includes a base edge 32 having a plurality of
17 perforations 34. In this embodiment, the anastomosis coupling
18 apparatus 30 can be fabricated from biocompatible polymers, such as
19 polyurethanes, silicones, polyurethane/silicone copolymers,
20 polyethylene, or nylon. Alternately, the anastomosis coupling
21 apparatus 30 can be comprised of biocompatible metals, such as
22 titanium or stainless steel. Furthermore, in some instances, it
23 may be desirable that the anastomosis coupling apparatus degrade
24 after the blood supplying vessel and coronary vessel have naturally
secured themselves together. In this instance, common

1 biocompatible and degradable materials, such as the poly-d,l-
2 lactate (lactide), poly-d,l-lactate-glycolate will be used as the
3 material for fabrication of the invention.

4
5 In the preferred process of forming the anastomosis coupling
6 from a polymer or degradable material, conventional processes
7 employing molds with various heat cycles appropriate for selected
8 material, will be used to fabricate the apparatus. If the
9 anastomosis coupling apparatus is fabricated from metal,
10 conventional machining techniques will be employed.

11 The anastomosis coupling apparatus 30 can also be made in
12 various sizes or configurations. In typically coronary
13 applications, the coupling will range from an inside diameter
14 between 0.5 mm to 10.0 mm, with a preferable range of 2.0 mm to 4.0
15 mm, depending on the overall diameter of the blood supplying vessel
16 and the particular application. The inside diameter of the input
17 end anastomosis coupling 30 must be large enough to accept a blood
18 vessel within its inner cavity without imparting undue trauma or
19 stress on the vessel. It can be appreciated that the exact inside
20 diameter is of relative importance, as it must function to provide
21 a secure bond between the inside surface of the anastomosis
22 coupling and the outside surface of the bypassing or blood
23 supplying vessel.
24

1 Also shown in this embodiment of the anastomosis coupling
2 apparatus 30 is a proximal end 31 which is the input end that
3 secures to the bypassing vessel for a blood supply. The distal end
4 33 has a lower rim 32 which has a plurality of perforations 34 used
5 to facilitate securement to the aperture 42 of a coronary vessel 40
6 with either stitches and/or staples.

7 The anastomosis coupling 30 can also deviate from the
8 configuration demonstrated in the Figures, whereby the overall
9 configuration more closely resembles a "Y", "V", or "U" shape.
10 Furthermore, the specifically configured anastomosis coupling 30
11 apparatus could have an acute angle between the longitudinal axis
12 of the input end and the longitudinal axis of the output. In
13 addition, the specifically configured anastomosis coupling
14 apparatus 30 might have a right deflection angle between a right
15 angle formed between the longitudinal axis of the input end and an
16 axis parallel the lip of a distal end of the input end, wherein
17 this deflection angle should be larger than 5 degrees. Also, the
18 specifically configured anastomosis coupling apparatus can have a
19 lip deflection angle between a right angle formed between the
20 longitudinal axis the input end and an axis parallel the lip of a
21 distal end of the input end, wherein this lip deflection angle is
22 larger than 5 degrees.

23 Now referring to FIGS. 3-5, it can be appreciated that the
24 coupler comprises two halves, 37 and 39, connected by a hinge

1 mechanism 36 located on the posterior side and separated apart from
2 slot 38 located on anterior side. This "clam shell" design
3 facilitates the proper placement of the supply vessel 10 within the
4 inner cavity defined between the two coupler halves. The by-
5 passing or blood supplying vessel should be positioned so that it
6 exits the lower rim 33 with an elongated shape to fit the shape of
7 the surgically opened aperture of the target coronary vessel.

8 The hinge mechanism 36 can comprise a simple indent or groove
9 made in the polymer fabrication material, or a more complex
10 arrangement in the metallic design.

11 Also, proper application of the adhesive or glue to outside
12 surface of the blood supplying vessel and to the inside surface 41
13 of the anastomosis coupling apparatus 30 is accomplished much
14 easier when separated.

15 Referring to FIG. 6, a target or coronary vessel 40 has been
16 surgically prepared to create an aperture 42 and exposing vessel
17 lumen 44. Blood flow is inhibited during this stage of the
18 procedure by using a clamp or similar mechanism (not shown) to
19 block blood flow. It is important that the operator use the size
20 and dimensions of the bypassing or blood supplying vessel as a
21 template in creating the aperture in the target vessel.
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1 In FIG. 7, the coupling apparatus 30 is shown in its opened
2 configuration and being prepared for securing the bypassing or
3 blood supply vessel 10 to the coupling apparatus 30. The operator
4 can place the bypassing or blood supplying vessel 10 into the
5 apparatus 20 without inflicting damage to the vessel 10 by using a
6 pair of forceps 52. At this time, tissue glue or adhesive 50 is
7 applied to the inner surface of the coupling apparatus 30 and
8 around the bypassing or blood supplying vessel 10. The glue or
9 adhesive 50 utilized to secure the severed end of the supply vessel
10 to the side wall of the target vessel may be any biocompatible glue
11 which gives sufficient strength to secure the outer surface of the
12 supplying vessel 10 in engagement with the inner surface of the
13 anastomosis coupler apparatus 30. Preferably, the glue is fast
14 acting, so that the region may be secured expeditiously. Examples
15 of such biocompatible glue are the fibrin glue sold under the trade
16 name "TISSEEL" manufactured by Immuno-U.S., Inc. of New York and a
17 gelatin-resorcine-formyl biological glue distributed by
18 Laboratories Cardial. Then, by closing the two halves or releasing
19 the opening force, the coupling apparatus 30 encloses the bypassing
20 or blood supplying vessel 10 within its cavity, securing the vessel
21 in place.

22 Now referring to FIG. 8, a highly compliant, (that matches the
23 inside diameter of the supplying vessel) deflated pear-shaped
24 balloon 49 is inserted into the distal lumen of the bypassed or
blood supplying vessel 10 and inflated to a very low pressure.

1 This process functions to assure that close engagement between the
2 outside surface of the vessel 10 and the inside surface of the
3 coupler apparatus 30, and even distribution of the adhesive, is
4 achieved. The desired result is a firm and secure attachment
5 between the two objects. The pear shaped balloon 49 assures that
6 the bypassing or blood supplying vessel assumes the elongated shape
7 of the apparatus 30. It is highly desirable to spread the distal
8 end of the vessel 10 around the distally funnel-shaped aperture of
9 the apparatus leaving a small excess from the vessel.

10 After removing the balloon 49 and trimming the excess section
11 of the supplying vessel 10, a functional and easy to handle
12 bypassed vessel and coupling apparatus combination 47 is formed.
13 As shown in FIG. 9, this combined apparatus is secured with a pair
14 of forceps and advanced towards the aperture 42 in the target
15 vessel 40. An anastomosis is created by performing a ligation
16 between the coupler apparatus combination 47 and the target vessel
17 40.

18 The two objects are secured together by threading stitches
19 through the perforations 34 and the lip of the aperture 42 in the
20 target vessel 10. It is also anticipated by the Applicant that, in
21 this embodiment, the operator can use medical grade staples in
22 place of, or in combination with, the stitches.
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1 The end result of using the present invention coupler is shown
2 in FIG. 10 (and FIG. 1) whereby the coupler/supplying vessel
3 combination 47 is firmly secured to the aperture 42 of the target
4 vessel 40 to eliminate blood leakage when forming the anastomosis.

5 Another embodiment of the present coupler invention is
6 demonstrated in FIGS. 11-14. In FIG. 11, the alternate anastomosis
7 coupler apparatus 70 is designed to facilitate a fast and simple
8 means to perform anastomose, which are typically required in
9 minimally invasive bypass procedures. In this embodiment, the
10 apparatus 70 has a wider base 72 which uses only small number of
11 stitches (situation stitches). The primary means for securement is
12 achieved by employing the adhesive techniques described herein. As
13 previously discussed, it can be appreciated that the coupler
14 comprises two halves connected by a hinge mechanism 76 located on
15 the lateral side and separated apart from slot 78 located on
16 anterior side. This "clam shell" design facilitates the proper
17 placement of the supply vessel 10 within the inner cavity defined
18 between the two coupler halves. The by-passing or blood supplying
19 vessel 10 should be positioned so that it exits the lower rim 72
20 with an elongated shape to fit the shape of the surgically opened
21 aperture of the target coronary vessel.

22 The hinge mechanism 76 can comprise a simple indent or groove
23 made in the polymer fabrication material, or a more complex
24 arrangement in the metallic design.

1 Also, proper application of the adhesive or glue to outside
2 surface of the blood supplying vessel and to the inside surface 41
3 of the anastomosis coupling apparatus 30 is accomplished much
4 easier when separated.

5 Although a particular form of the invention has been
6 illustrated and described, it will be appreciated by those skilled
7 in the art that various modifications can be made without departing
8 from the spirit and scope of the invention. Accordingly, the scope
9 of the present invention is not to be limited by the particular
10 embodiments above, but is to be defined only by the following
11 claims.